OCT 1 8 2004

K033943

510(k) Premarket Notification
Alpha Metasul 28mm and 32mm Acetabular Inserts, Standard and Hooded

510(k) SUMMARY

MANUFACTURER: Centerpulse Orthopedics, Ltd. (a division of Zimmer)
Altgasse 44
CH-6340
Baar, Switzerland

SPONSOR: Centerpulse Orthopedics, Inc. (a division of Zimmer)
9900 Spectrum Drive
Austin, TX 78717 USA

CONTACT: Audrey Swearingen
Phone: (512) 432-9255
E-Mail: Audrey.Swearingen@zimmer.com

TRADE NAME: Alpha Metasul® 28mm and 32mm Acetabular Inserts, Standard and Hooded

COMMON NAME: Total hip replacement system acetabular insert

CLASSIFICATION: CFR §888.3330 (KWA) - Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis. Metal-on-metal hip prostheses are Preamendment Class III devices.

PREDICATE DEVICES:

- Centerpulse Orthopedics Inc. Allofit™ Acetabular System, Alpha Metasul® Acetabular Insert, 28mm Standard and Hooded (K003758)
- Biomet M2a™ Ringloc® Acetabular Liner (K002379)
- Biomet M2a -Taper™ Acetabular System (K003363)

DEVICE DESCRIPTION:

The Alpha Metasul Acetabular Insert (28mm and 32mm) is a hemispherically shaped design, composed of an outer component manufactured from polyethylene (UHMWPE) (in compliance with ISO 5834-1/2) which is thermo-mechanically bonded to a wrought hot-forged CoCr alloy metallic inlay (in compliance with ISO 5832-12 and ASTM F1537). The Alpha Metasul Acetabular Insert is designed for use only with a Metasul femoral head component, as a metal-on-metal system. The body's natural synovial fluid lubricates the metal surfaces.

The Alpha Metasul 32mm Acetabular Insert, both standard and hooded, is available in sizes designed to mate with Allofit™ Acetabular Shells, sizes 52mm to 68mm (in 2mm increments). In turn, the proposed Alpha Metasul 28mm insert is available in sizes designed to mate with Allofit™ Acetabular Shells, sizes 48mm to 68mm (in 2mm increments). Both insert sizes have the same basic design as the previously cleared Alpha Metasul 28mm Acetabular Insert, standard and hooded. They also share many characteristics with Biomet's M2a Ringloc Acetabular Liner and M2a -Taper Acetabular System.

The Alpha Metasul Insert has what is commonly referred to as a "poly-sandwich" design. The inner diameter, which forms the bearing surface of the insert, features a metallic

Metasul inlay that is polished to a mirror-finish and thermo-mechanically bonded into the polyethylene liner, which is then locked into the Allofit acetabular shell via the proven snap mechanism. On the hooded inserts, the face of the polyethylene outer diameter incorporates an overhang of polyethylene extending superiorly from the midpoint of the insert face. This hood feature is designed to provide additional resistance to subluxation and instability.

INTENDED USE:
The Alpha Metasul 28mm and 32mm Acetabular Inserts, standard and hooded, are intended for use in total hip arthroplasty for treatment of the following:

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis;
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- Revision of previously failed hip arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Performance tests, design comparisons, indications for use and labeling of the Alpha Metasul 28mm and 32mm Acetabular Inserts (standard and hooded) demonstrate that they are substantially equivalent in terms of design features, materials, and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Ms. Audrey Swearingen
Manager, Regulatory Affairs
Zimmer, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K033943
Trade/Device Name: Alpha™ Metasul® 28mm and 32mm Acetabular Insert
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: September 24, 2004
Received: September 27, 2004

Dear Ms. Swearingen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033943

Device Name: Alpha™ Metasul® 28mm and 32mm Acetabular Insert

Indications for Use:

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- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis;
- those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- revision of previously failed hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033943

(Posted November 13, 2003)